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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,437	10/15/2001	Jeffrey A. Heroux	2528-8	3932

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,437	HEROUX ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-67,69 and 77-87* is/are pending in the application.

4a) Of the above claim(s) *77-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-67,69 and 81-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December14, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on December 14, 2005. Currently claims 45-67, 69, 81-87are pending. Claims 45-46, 50-51, 54-56, 60-61, 64 are amended. Claims 1-44, 68, 70-76 and 88 are cancelled. Claims 77-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

Informalities

3. The specification contains following informalities:

Claims 54, 64, 66, 83-84, 87 recite an improper Markush group. A recitation of "selecting from the group consisting of" is suggested.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 51 recites 'enzyme forms a covalent bond' which is indefinite and unclear because it is not clear whether the enzyme forms a covalent bond with the first substrate or the second substrate or both or with the luminescence label.

Claim Interpretation

5. The enzyme that modifies the rate of joining a first substrate with a second substrate is broadly interpreted as a DNA polymerase.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 45-54, 69, 81-82, 85, 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over comb et al. (USPN. 5,834,285) in view of Massey et al. (USPN. 5,866,434).

Comb et al. teach a method for assaying a sample for enzyme activity (DNA polymerase activity) that modifies the rate of joining a first substrate (DNA fragment of M13mp18 DNA) with a second substrate (complementary DNA fragment of M13mp18 DNA) to form a product (amplification product) comprising

(a) forming a composition comprising said sample (DNA polymerase) said first and second first and second substrates (See col. 31, line 54-67, col. 32, line 15-27),

(b) incubating said composition under conditions that form said product in the presence of said enzyme, wherein said enzyme activity is not a part of the product (see col. 32, line 15-27),

(e) measuring the presence of the product as an indication of said enzyme activity in said sample (see col. 32, line 27-43).

With regard to claim 53, 63, Comb et al. teach that said first and second substrates comprise nucleic acids (see col. 31, line 54-62),

With regard to claim 54, comb et al. teach that the enzyme is a nucleic acid polymerase (see col. 31, line 54-62).

With regard to claims 55-56, 60-61, 64, Comb et al. teach that said polymerase has a nuclease activity (see col. 31, line 54-62, polymerase inherently has exonuclease activity),

With regard to claim 87, Comb et al. teach that said factor is a denaturing compound (see col. 32, line19-22).

However, Comb et al. did not teach measuring said enzyme activity using a luminescent label immobilized on an electrode and measuring the emitted luminescence as an indication of said enzyme activity.

Massey et al. teach a method of claims 45-46, 50, of assaying a sample for an activity that modifies the rate of joining that joins (binds) a first substrate (an assay-performance substance) and a second substrate (a functionalized graphic nanotube) to form a product (binding complex) comprising:

(a) forming a composition comprising said sample, said first and second substrate (see col. 13, line 9-19, line 31-43);

(b) incubating said composition to form said product (see col. 13, line 20-22, line 44-45);

(c) immobilizing a luminescent label linked to said product on an electrode (see col. 13, line 15-22, line 31-45);

(d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see col. 13, lines 24-27, line 48-51);

(e) measuring emitted luminescence to measure said activity (see col. 13, line 29-31, line 52-54).

With regard to claim 46-47, 85, Massey et al. teach that said first substrate is linked to a luminescent label (see col. 13, line15-17) and said second substrate linked (attached) to electrode (magnetically responsive nanotubes) (see col. 13, line 18-19);

With regard to claim 47, 50, 81-82, Massey et al. teach that the second substrate is linked (attached) to said electrode via avidin (capture moiety) biotin linkage (see col. 40, line 41-50);

With regard to claims 48-49, Massey et al. teach that said electrode (nanotube fibrils) linked to one or more additional substrates forming a patterned array of substrates comprising at least two substrates that differ in structure (see col. 52, line 27-67, col. 53,

line 1-2, wherein nanotube fibril comprises biotinylated fibril and alkylated biotinylated fibrils having two different structures);

With regard to claims 52-53, Massey et al. teach that said first substrate comprises peptides and nucleic acids (see col. 16, line 45-64);

With regard to claim 51, Massey et al. teach that said activity (binding activity) results in the formation of a covalent bond (see col. 10, line 13-37, wherein the complex formed with Y indicates a covalent bond);

With regard to claim 67, Massey et al. teach said electrode comprises conductive particles with in or on a polymeric material (see col. 11, line 47-67, col. 12, lines 1-28);

With regard to claims 54, 68, 87, Massey et al. teach that said activity is an enzyme activity comprising catalytic enzymes as glucosidases, dehyrogenases (see col. 47, line 10-15, col. 49, line 55-67, col. 50, line 1-67);

With regard to claim 65-66, said electrode comprises elemental carbon in the form of graphite (see col. 13, line 18-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of assaying enzyme activity as taught by Comb et al. with a step of luminescent label on an electrode as taught by Massey et al. for the purpose of enhancing the efficiency of detecting the enzyme activity in said sample. One skilled in the art would be motivated to combine the method as taught by Comb et al. with the chemiluminescent label detection as taught by Massey et al. because Massey et al. explicitly taught that the use of luminescence assays using particles having high surface area for immobilization of assay performance substances to achieve advantageously high light emission (see col. 6, line 24-27). The ordinary artisan would

have a reasonable expectation of success that inclusion of said luminescence assay system to detect said enzyme activity taught by Comb et al. would result in increase in the sensitivity of detection of said enzyme and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

B. Claims 55-67, 69, 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shivaraja (USPN. 6,569,619) in view of Massey et al. (USPN. 5,866,434).

Shivaraja teaches a method of claim 55-56, 60, for assaying a sample for enzyme activity (DNA helicase) that cleaves a substrate (nucleic acid fragment) comprising

(a) forming a composition comprising said sample (DNA helicase) a first and second nucleic acid substrates (see col. 2, line 20-25),

(b) incubating said composition under conditions wherein said enzyme can cleave said substrate (see 2, line 20-27),

(c) immobilizing a nucleic acid with a label tag to the reaction mixture (see col. 2, line 27-35)

(e) measuring the activity for the presence of the enzyme (see col. 2, line 35-38).

With regard to claim 63, Shivaraja teaches that said substrate comprise nucleic acids (see col. 2, line 20-25),

With regard to claim 64, Sivaraja teaches that the enzyme is a nuclease (see col. 2, line 20-27).

With regard to claim 87, Shivaraja teaches that said factor is a denaturing compound (see col. 12, line 56-67).

However, Shivaraja did not teach measuring said enzyme activity using a luminescent label immobilized on an electrode and measuring the emitted luminescence as an indication of said enzyme activity.

Massey et al. teach a method of claims 45-46, 50, of assaying a sample for an activity that modifies the rate of joining that joins (binds) a first substrate (an assay-performance substance) and a second substrate (a functionalized graphic nanotube) to form a product (binding complex) comprising:

(a) forming a composition comprising said sample, said first and second substrate (see col. 13, line 9-19, line 31-43);

(b) incubating said composition to form said product (see col. 13, line 20-22, line 44-45);

(c) immobilizing a luminescent label linked to said product on an electrode (see col. 13, line 15-22, line 31-45);

(d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see col. 13, lines 24-27, line 48-51);

(e) measuring emitted luminescence to measure said activity (see col. 13, line 29-31, line 52-54).

With regard to claim 46-47, 85, Massey et al. teach that said first substrate is linked to a luminescent label (see col. 13, line15-17) and said second substrate linked (attached) to electrode (magnetically responsive nanotubes) (see col. 13, line 18-19);

With regard to claim 47, 50, 81-82, Massey et al. teach that the second substrate is linked (attached) to said electrode via avidin (capture moiety) biotin linkage (see col. 40, line 41-50);

With regard to claims 48-49, Massey et al. teach that said electrode (nanotube fibrils) linked to one or more additional substrates forming a patterned array of substrates comprising at least two substrates that differ in structure (see col. 52, line 27-67, col. 53, line 1-2, wherein nanotube fibril comprises biotinylated fibril and alkylated biotinylated fibrils having two different structures);

With regard to claims 52-53, Massey et al. teach that said first substrate comprises peptides and nucleic acids (see col. 16, line 45-64);

With regard to claim 51, Massey et al. teach that said activity (binding activity) results in the formation of a covalent bond (see col. 10, line 13-37, wherein the complex formed with Y indicates a covalent bond);

With regard to claim 67, Massey et al. teach said electrode comprises conductive particles with in or on a polymeric material (see col. 11, line 47-67, col. 12, lines 1-28);

With regard to claims 54, 68, 87, Massey et al. teach that said activity is an enzyme activity comprising catalytic enzymes as glucosidases, dehyrogenases (see col. 47, line 10-15, col. 49, line 55-67, col. 50, line 1-67);

With regard to claim 65-66, said electrode comprises elemental carbon in the form of graphite (see col. 13, line 18-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of assaying enzyme activity as taught by Shivaraja with a step of luminescent label on an electrode as taught by Massey et al. for the purpose of enhancing the efficiency of detecting the enzyme activity in said sample. One skilled in the art would be motivated to combine the method as taught by Comb et al. with the chemiluminescent label detection as taught by Massey et al. because

Massey et al. explicitly taught that the use of luminescence assays using particles having high surface area for immobilization of assay performance substances to achieve advantageously high light emission (see col. 6, line 24-27). The ordinary artisan would have a reasonable expectation of success that inclusion of said luminescence assay system to detect said enzyme activity taught by Shiavaraja would result in increase in the sensitivity of detection of said enzyme and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

7. With regard to the rejection under 35 USC 112, first paragraph (new matter rejection), Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment.

8. With regard to the rejection under 35 USC 102(b) as being anticipated by Leland et al., Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejections.

9. With regard to the rejection under 35 USC 102(e) as being anticipated by Massey et al., Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-

272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru 2/17/06
Patent Examiner
Art Unit 1637